JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION, Plaintiff, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	CASE NO. CV 11-07925 MMM (JEMx) JUDGMENT FOR PLAINTIFFS

On August 6, 2013, the court granted in part and denied in part the United States Food and Drug Administration's ("FDA") motion for summary judgment against plaintiff Aids Healthcare Foundation ("AHF"), and *sua sponte* granted summary judgment in favor of AHF with respect to the FDA's obligation to disclose certain documents under the Freedom of Information Act ("FOIA"). The court deferred ruling on several additional documents and directed the FDA to submit a more detailed affidavit and/or *Vaughn* index and to produce certain documents for *in camera* inspection by the court. On February 13, 2014, the court decided the remaining outstanding issues. It granted in part and denied in part the FDA's motion, and *sua sponte* entered summary judgment in favor of AHF with respect to certain documents.

THEREFORE, IT IS ORDERED AND ADJUDGED

1. That defendant FDA is ordered to produce the following records in their entirety, except for the information that this judgment specifies can be redacted. For ease of reference, the documents are identified below as described by the FDA in its *Vaughn* indices, as well as by their accompanying "CDER" numbers. Where the court has referred in its orders to documents using multiple descriptions of the same document, the court lists the document under each description. The documents the FDA is directed to produce are:

   a. "datasets" supporting Gilead's NDA, which pertain to its "efficacy analysis": CDER Nos. 2-3, 391-396, 465-467, 473-477, 1299, 1315-1318, 1406, 1506-1511, 149074-149076, and 155415;

   b. "datasets" supporting Gilead's NDA, pertaining to its "safety analysis" CDER: Nos. 432, 150300-150302, 150304-150306, 150312, 150670, 150671, 150672, 150783, 150785, and 150787;

   c. "safety and efficacy information" and "efficacy and safety data": CDER Nos. 1437-1481, 148218-148223, 1515-148185 (redacting information withheld under Exemption 6 for CDER Nos. 1560, 1604, 1607-1609, 1801, 5137-5160, 5162-5165, 5167-5188, and 5190-5218);

   d. "raw data": CDER Nos. 1515-148185 (redacting information withheld under Exemption 6 for CDER Nos.1560, 1604, 1607-1609, 1801, 5137-5160, 5162-5165, 5167-5188, and 5190-5218);

   e. "adherence data": see, e.g., CDER Nos. 1515-148185 (redacting information withheld under Exemption 6 for CDER Nos.1560, 1604, 1607-1609, 1801, 5137-5160, 5162-5165, 5167-5188, and 5190-5218);

   f. "study data": CDER Nos. 410-418, 457-912, 1520-5521 (redacting information withheld under Exemption 6 for CDER Nos.1560, 1604, 1607-1609, 1801, 5137-5160, 5162-5165, 5167-5188, and 5190-5218), 148202-148210, and 152416-152419;

g. "diagnostic results": CDER Nos. 1515-148185 (redacting information withheld under Exemption 6 for CDER Nos.1560, 1604, 1607-1609, 1801, 5137-5160, 5162-5165, 5167-5188, and 5190-5218);

h. "data interpretation records": CDER Nos. 149464 (redacting all information except for the statement that "The iPrEx trial demonstrated a 44% reduction in the incidence of HIV-1 infection in the FTC/TDF group relative to placebo"), 149987-149988, 149990-149993, 150298-150306, 150311, 150312, 150316-150318;

i. "second Medguides email": CDER Nos. 151471-151482 (redacting all of the medical officer's track changes, comments and edits)

j. "meeting minutes documents": CDER Nos. 150776-150778; and

2. That the action be, and it hereby is, dismissed.

DATED: February 13, 2014

Margaret M. Morrow

MARGARET M. MORROW
UNITED STATES DISTRICT JUDGE